OPERATOR AND SERVICE MANUAL

CARDIO VIVE™ *AT*

BURDICK®

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PATENTS

This device is covered by the following U.S. and foreign patents:

5,792,190; 5,999,493; 5,402,884; 5,579,919; 5,749,902; 5,645,571; 6,029,085; 5,984,102; 5,919,212; 5,891,172; 5,674,266; 5,700,281; 5,891,173; 5,968,080; 6,263,239; 5,797,969; D402,758; D405,754; 5,909,138; 6,173,203; 6,088,616; 5,897,576; 5,955,956; 6,083,246; 6,064,909; 6,038,473; 5,868,794; 6,115,638; 6,366,809; 5,474,574; 6,246,907; 6,289,243; 6,411,846; 6,480,734; 6,658,290; EP00756878

Other U.S. and foreign patents pending.

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Limited Warranty

Limited Warranty Cardiac Science Corp. ("Cardiac Science") warrants to the original purchaser that its AEDs and stated battery operating life will be free of any defect in material and workmanship according to the terms and conditions of this Limited Warranty ("Limited Warranty"). For purposes of this Limited Warranty, the original purchaser is deemed to be the original end user of the product purchased. This Limited Warranty is NONTRANSFERABLE and UNASSIGNABLE.

For How Long? Seven (7) years from the date of the original shipment to the original purchaser for CardioVive AT automated external defibrillators. Disposable defibrillation pads shall be warranted until the expiration date. Lithium batteries P/N (p/n: 9146-001-C1) have a full operational replacement warranty of four (4) years from the date of installation into a CardioVive AT AED. One (1) year from the date of original shipment to the original purchaser for Cardiac Science AED accessories. The terms of the Limited Warranty in effect as of the date of original purchase will apply to any warranty claims.

What You Must Do Please complete and submit the warranty card or internet warranty form (www.burdick.com/support/warranty_registration.htm) within 30 days of original shipment.

To obtain warranty service for your product, call us toll free. Our technical service representative will try to resolve your issue over the phone. If necessary, and at our sole discretion, we will arrange for service or a replacement of our product.

What We Will Do: If your product is returned within 30 days of the date it was purchased, at the direction of a technical service representative, we will replace it with a new product of equal value at no charge to you, provided the warranty applies.

If your Cardiac Science product is returned, at the direction of a technical service representative, after 30 days but within the warranty period, Cardiac Science, at its sole discretion, will repair your product or replace it. The repaired or replacement product will be warranted subject to the terms and conditions of this Limited Warranty for either (a) 90 days or (b) the

remainder of the original warranty period, whichever is longer, provided the warranty applies and the warranty period has not expired.

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What This Warranty Does Not Cover This Limited Warranty does not cover defects or damages of any sort resulting from, but not limited to, accidents, damage while in transit to our service location, alterations, unauthorized service, unauthorized product case opening, failure to follow instructions, improper use, abuse, neglect, fire, flood, war or acts of God. Cardiac Science

makes no warranty claim as to the compatibility with Cardiac Science products with non Cardiac Science products.

This Limited Warranty is Void if:

- Any Cardiac Science product is serviced or repaired by any person or entity other than Cardiac Science unless specifically authorized by Cardiac Science.
- Any Cardiac Science product case is opened by unauthorized personnel or if a product is used for an unauthorized purpose.
- Any Cardiac Science product is used in conjunction with incompatible parts or accessories, including but not limited to batteries. Parts and accessories are not compatible if they are not Cardiac Science products or the functional equivalent.

If The Warranty Period has Expired If your product is not covered by our Limited Warranty, call us toll free for advice as to whether we can repair your Cardiac Science product, and for other repair information, including charges. Charges for non-warranty repairs will be assessed and are your responsibility. Upon completion of the repair, the terms and conditions of this Limited Warranty shall apply to such repair or replacement product for a period of 90 days.

This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state.

1 Product Information and Safety

What's in this chapter

- Safety Terms and Definitions
- Product Models
- Safety Alert Descriptions
- Symbol Descriptions

Before Operating the CardioVive AT AED:

Become familiar with the product information and various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the CardioVive AT AED.

Contact Information

To order additional CardioVive AT AEDs or accessories worldwide:

- Toll Free: 800.991.5465
- Telephone: 425.402.2690
- Fax: 425.402.2001
- Email: customerservice@cardiacscience.com

To receive 24-hour customer support:

There is no charge to the customer for a customer support call. Please have the serial and model numbers available when contacting Customer Service. (The serial and model numbers are located on the underside of the AED.)

- Toll Free: +1.888.466.8686
- Telephone: +1.425.402.2691
- Email: techsupport@cardiacscience.com
- Website: www.cardiacscience.com

Defibrillator Tracking

Defibrillator manufacturers and distributors are required, under the Safe Medical Devices Act of 1990, to track the location of defibrillators they sell. Please notify Cardiac Science Customer Service in the event that your defibrillator is sold, donated, lost, stolen, exported, destroyed or if it was not purchased directly from Cardiac Science Corp. or an authorized dealer.

Product Models

This manual is for use with the following AED models:

- CardioVive AT

"CardioVive AT AED", "AED" or "device" refers to the models listed above unless otherwise noted.

Safety Terms and Definitions

The symbols shown below identify potential hazard categories. The definition of each category is as follows:

DANGER

This alert identifies hazards that will cause serious personal injury or death.

WARNING

This alert identifies hazards that may cause serious personal injury or death.

CAUTION

This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

Safety Alert Descriptions

The following is a list of CardioVive AT AED safety alerts that appear in this section and throughout this manual.

Read and understand these safety alerts before operating the AED.

DANGER: Fire and Explosion Hazard

Do not use in the presence of flammable gasses (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard

Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not use in standing water or rain. Move patient to dry area
- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage.

Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Electric Shock and Fire Hazard.

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

WARNING: Battery is Not Rechargeable.

Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

WARNING: Shock Hazard.

Do not disassemble the AED. Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.

WARNING: Possible Radio Frequency (RF) Susceptibility.

RF susceptibility from cellular phones, CB radios, and FM 2-way radios may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

WARNING: Possible Interference with Implanted Pacemaker.

Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock. (Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4)

When placing Pads:

- Do not place the pads directly over an implanted device.
- Place the pad at least one inch from any implanted device.

CAUTION: Restricted Use.

Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

CAUTION: Read this Operation and Service Manual carefully.

It contains information about your safety and the safety of others. Become familiar with the controls and how to use the AED properly before operating the product.

CAUTION: Temperature Extremes.

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AED's operating parameters, a "Service Required" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Chapter 7, *Technical Data*.

CAUTION: Lithium Sulfur Dioxide Battery.

Pressurized contents: never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Battery Disposal.

Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only Cardiac Science Approved Equipment.

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance.

Using pads that are damaged or expired may result in improper AED performance.

CAUTION: Serial Communication Cable.

The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove Cable to Continue Rescue" will be heard until you remove the serial communication cable.

CAUTION: Moving the Patient During a Rescue.

During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

CAUTION: Serial Communication Cable.

The serial communication cable is only for use with the AED; it is not to be used with a telephone.

CAUTION: Systems Statement.

Equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 601-1 for medical equipment).

Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 601-1-1.

CAUTION: Case Cleaning Solutions.

When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

Symbol Descriptions

The following symbols may appear in this manual, on the AED, or on its optional components. Some of the symbols represent standards and compliances associated with the AED and its use.

Table 1: Symbol Descriptions

Symbol	Description
	Caution. Consult accompanying documentation.
	Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED.
	Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.
	CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.
IP24	The AED is protected against the effects of splashing water in accordance with IEC 60529.
	Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4.Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.
	International symbol for ON. Open the lid to turn on the AED.

Table 1: Symbol Descriptions

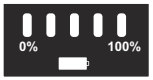
Symbol	Description
	Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.
	Check pads. The pads are missing, not connected or have compromised functionality.
	Indicates AED requires maintenance by authorized service personnel.
	When the SHOCK indicator is lit, push this button to deliver a defibrillation shock.
	When the CONTINUE indicator is lit, push this button to clear the internal memory to allow storage of new rescue data in the AED. (Only for models not equipped with Multiple Rescue software)
	A red indicator with a BLACK X means the AED requires operator attention or maintenance, and is not RescueReady.
	A green indicator without a BLACK X means the AED is RescueReady.
	Use pads by this date.

Table 1: Symbol Descriptions

Symbol	Description
	Date of manufacture, year and month.
	Date of factory recertification (R).
	Latex free.
	Disposable. Single patient use only.
	Tear here to open.
	Do not recharge battery.
	Position of pads on the chest of patient.
	For use by or on the order of a Physician, or persons licensed by state law.

Table 1: Symbol Descriptions

Symbol	Description
	Dispose of properly in accordance with all state, province, and country regulations.
	Do not incinerate or expose to open flame.
	Explosion hazard: Do not use in the presence of a flammable gas, including concentrated oxygen.
	Upper and lower temperature limits.
	Serial Number.
	Device model number, battery model number.
	Lot number
	Option number

Table 1: Symbol Descriptions

Symbol	Description
	Lithium sulfur dioxide
	Serial communication port
	Additional information is provided in the AED Operation and Service Manual.
	Manufacturer
	Authorized representative in the European Community
	Waste Electronic Electrical Equipment (WEEE). Separate collection for waste electrical and electronic equipment.

2 Introduction

What's in this chapter

- AED Description
- Indications for Use
- RHYTHMx AED ECG Analysis Algorithm
- Rescue Protocol
- STAR Biphasic Waveform
- STAR Biphasic Energy Protocols for CardioVive AT AEDs

This section presents information about the AED, its use, and the training requirements for operation.

AED Description

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's electrodes (pads) to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to push the button and deliver a shock if needed.

Indications for Use

The AED with STAR Biphasic Waveform is intended to be used by personnel who have been trained in its operation. The operator should be qualified by training in basic life support, CPR/AED, or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. If the victim is breathing post-resuscitation, the AED should be left attached to allow for acquisition and detection of the ECG rhythm.

If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Pads. Therapy should not be delayed to determine the patient's exact age or weight.

RHYTHMx AED ECG Analysis Algorithm

The RHYTHMx® AED ECG analysis algorithm provides ECG detection capabilities, The features available with the AED include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate

Detection Rate

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is programmable between 120 bpm (beats per minute) and 240 bpm via MDLink Software by the Medical Director. The default Detection Rate is 160 bpm.

Asystole Threshold

The asystole peak-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as asystole and will not be shockable.

Noise Detection

The AED will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED will issue the prompt "Analysis Interrupted. Stop Patient Motion" to warn the operator.

The AED will then proceed to reanalyze the rhythm and continue with the rescue.

Non-Committed Shock

After the AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt "Rhythm Changed. Shock Cancelled." The AED will override the charge and initiate CPR.

Synchronized Shock

The AED is designed to automatically attempt to synchronize shock delivery on the R-wave if one is present. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

Pacemaker Pulse Detection

The AED contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.

SVT Discriminators

The AED is supplied with the SVT Discriminator enabled and with the default setting "NO THERAPY FOR SVT". With the factory default setting of "NO THERAPY FOR SVT", the AED will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is "NO THERAPY FOR SVT", however the Medical Director can enable this feature using MDLink.

SVT Rate

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable

between 160 and 300 bpm or, “NO THERAPY FOR SVT” can be selected via MDLink Software by the Medical Director.

Rescue Protocol

The AED rescue protocol is consistent with the guidelines recommended by the American Heart Association (*Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, American Heart Association*; Circulation Vol 112, Issue 24 Suppl. Dec 13, 2005) and the International Liaison Committee on Resuscitation (ILCOR)).

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button to deliver a shock and then advises the operator to start CPR.

Note: The standard CPR protocol of 120 seconds can be modified from 60 to 180 seconds in MDLink.

STAR Biphasic Waveform

The STAR® Biphasic Waveform is designed to measure the patient’s impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. The energy levels for the CardioVive AT AED are available in three different defibrillation shock.

The ultra-low current, low current, and high current shocks are variable energy. The actual energy is determined by the patient’s impedance) configurations. See table on next page and Chapter 7 for additional information.

STAR Biphasic Energy Protocols for CardioVive AT AEDs

The STAR Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient’s needs based upon a patient’s thoracic impedance. This customization adjusts for the unique physical differences between patients. The CardioVive AT AED comes equipped with five different FDA cleared biphasic energy protocols.

The operator, with guidance, direction and implementation from the designated AED program Medical Director, may select from one of these five protocols when placing the CardioVive AT AED into service. The

CardioVive AT AEDs factory default energy protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 126J-260J. Subsequent shocks are delivered within a range of 170J-351J.

These protocols are selected by using our MDLink software program. The five biphasic energy protocols available are as follows:

Table 2: Biphasic Energy Protocols

Energy Protocols	Shock Sequence[1]	Energy Level (VE)	Energy Range (J)[2]
Factory Default	1	200	126-260
	2	300	170-351
	3	300	170-351
Protocol #2	1	200	126-260
	2	200	126-260
	3	300	170-351
Protocol #3	1	150	95-196
	2	200	126-260
	3	200	126-260
Protocol #4	1	150	95-196
	2	150	95-196
	3	200	126-260
Protocol #5	1	200	126-260
	2	200	126-260
	3	200	126-260

[1]The Ultra-Low Energy (150 VE), Low Energy(200 VE), and High Energy(300 VE) shocks are variable energy. The actual energy is determined by the patient's impedance.

[2] Available energy range.

Operator Training Requirements

Persons authorized to operate the AED must have all of the following minimum training.

- Defibrillation training and other training as required by state, province, or country regulations
- Training on operation and use of the AED
- Additional training as required by the physician or Medical Director
- A thorough understanding of the procedures in this manual

Note: Keep valid certificates of training and certification as required by state, province, or country regulations.

3 Getting Started

What's in this chapter

- Unpacking and Inspecting
- AED Parts
- AED Modes
- IntelliSense Battery
- Pads
- AED Indicators
- Setting the AED Internal Clock
- Voice Prompts and Text Display

This section presents information on unpacking and setting up the AED

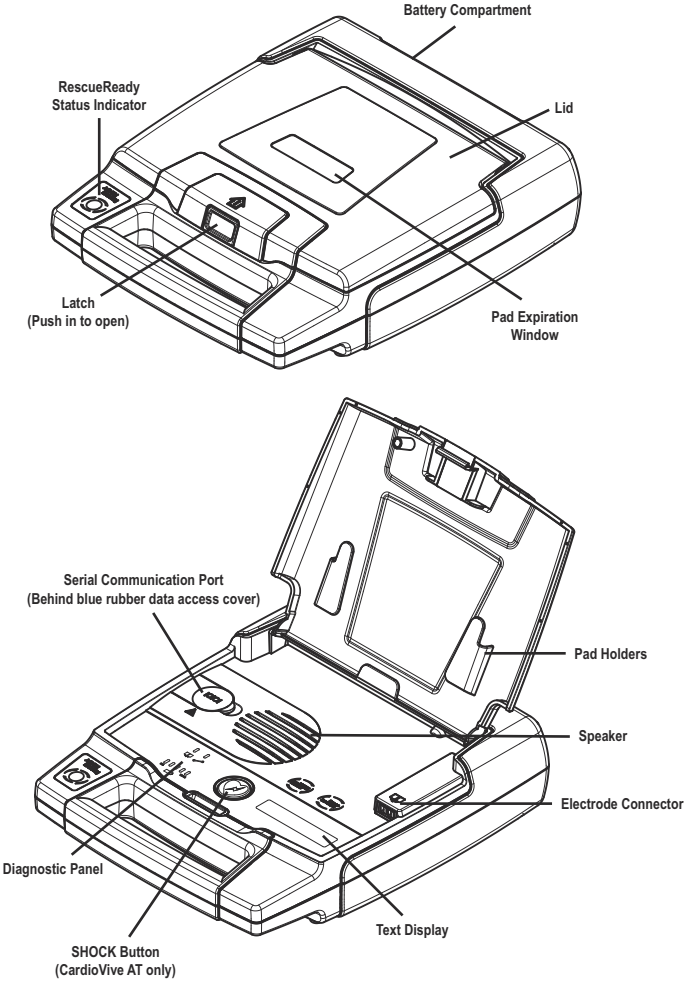
Unpacking and Inspecting

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

If you have any questions about your order, contact Customer Service. See page 4.

AED Parts

The following drawings show the AED parts and their locations.



AED Modes

Operating Mode: Defined as having the battery installed and the lid open. This is the mode the AED would be in during an actual rescue situation.

Standby Mode: When the battery is installed, but the lid is closed. In this mode the AED is not being used in a rescue. The device will conduct its routine self-tests to ensure proper operation.

Storage Mode: When the battery is removed, such as during shipping or transport. With the battery removed, the AED is unable to perform self-tests or rescues.

Environmental Operating and Standby Conditions

See Chapter 7, *Technical Data*.

Caution. Temperature Extremes.

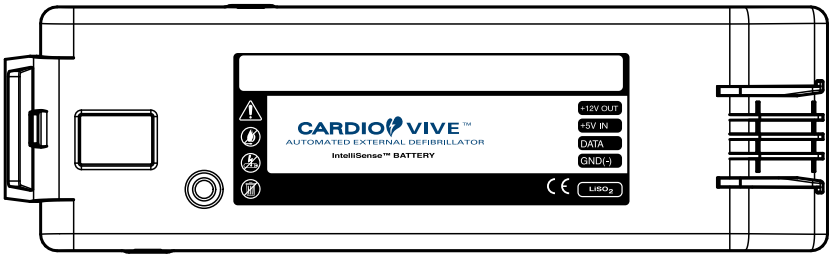
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AEDs operating parameters, a "Service Required" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once.

Shipping and Transport Conditions

See Chapter 7, *Technical Data*.

IntelliSense Battery

IntelliSense batteries contain an integrated memory chip that automatically stores important usage information, enabling the battery to maintain a complete history of its operating life. The actual battery history can be reviewed using the RescueLink software.



This history includes:

- Battery Identification
- Battery Type
- Original Date of Installation in an AED
- Number of Charges completed
- Time in Operation (hours:minutes)
- Days of Standby Operation
- Battery Capacity Remaining

Danger. Battery is Not Rechargeable.

Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

Caution. Lithium Sulfur Dioxide Battery.

Pressurized contents: never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

Caution. Battery Disposal.

Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

Caution. Use only Cardiac Science Approved Equipment.

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

Caution. Possible Improper AED Performance.

Using pads that are damaged or expired may result in improper AED performance.

Battery Operating Life

The battery operating life depends on the type of battery, actual usage and environmental factors.

The following table represents the expected life of the CardioVive AT AED when used in Standby Mode.

Table 3: Normal Battery Operating Life

Model	Estimated Shelf Life (from date of manufacture)	Full Operational Replacement Guarantee (from date of installation)	Typical Shocks
9146 Lithium (p/n: 9146-001-C1)	5 Years	4 Years	up to 290

Battery Shelf Life

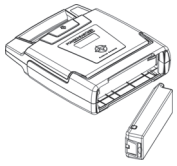
The batteries have a shelf life of five years. Shelf life is defined as the length of time a battery can be stored, prior to installation into AED, without degrading its performance.

Note: Storing the battery outside its specific range (0-50°C) will decrease battery life.

Battery Installation

To install the battery:

1 With the label on the battery facing the AED battery compartment, insert the battery as shown in the drawing.



2 Push the latched end of the battery firmly into the AED, as shown in the drawing, until the battery snaps into place. The exposed side of the battery should be flush with the outside of the AED case.

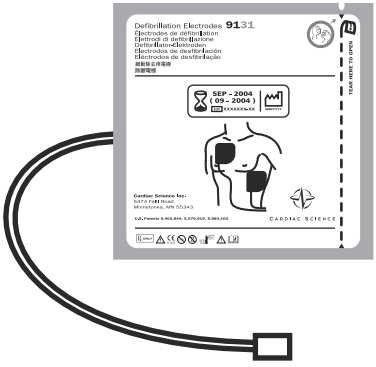
3 Open the lid for 5 seconds to initiate a self-test. If the battery is installed properly, the SMARTGAUGE battery indicator LEDs will illuminate and the STATUS INDICATOR will turn GREEN. If service is required, then the SERVICE indicator will illuminate; call for service.

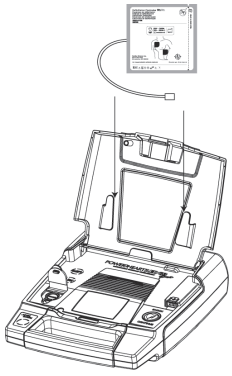
Pads

The defibrillation pads come in a ready-to-use, sealed package containing one pair of self-adhesive pads with an attached cable and connector. The pads are disposable and should be discarded after each rescue.

The pads have a limited shelf life and should not be used beyond the expiration date. Keep a fresh, unopened pair of pads plugged into the AED at all times. Refer to the pad package label for operation temperatures.

An audible and visual alert will indicate after the self-test if the pads are missing, unplugged or damaged.





Pad Installation

To install the pads:

1. Open the lid of the AED.
2. Place the pad package into the lid so that the expiration label is visible through the clear window on the lid. The expiration date of the pads will then be readable without opening the lid of the AED.
3. Match the color of the connectors (red to red), then plug the pad connector into the AED case as shown in the drawing. Once the pad connector is plugged into AED, the PAD indicator should extinguish.
4. Tuck the excess cable length in the bottom holder as shown in the drawing. With the pad package completely secured to the AED lid, close the lid.
5. Make sure the expiration date is visible through the clear window of the lid and check to make sure that the STATUS INDICATOR is GREEN. If the pads are not installed properly, the STATUS INDICATOR will be RED; call Customer Service for assistance.

Caution. Use only Cardiac Science Approved Equipment.

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

Caution. Possible Improper AED Performance.
Using pads that are damaged or expired may result in improper AED performance.

Directions for Use

Pads are for short term use only. Do not open until ready to use.

1. Ensure the skin site is clean and dry.
2. Separate one pad from liner.
3. Place one pad on skin in either location.
4. Peel and place remaining pad.

AED Indicators

The following indicators are located on the AED.

RescueReady Status Indicator

The STATUS INDICATOR is located on the CardioVive AT AED handle.

When this indicator is GREEN, the AED is RescueReady. This means the AED self-tests have verified the following:

- Battery has an adequate charge
- Pads are properly connected to the AED
- Integrity of the internal circuitry is good

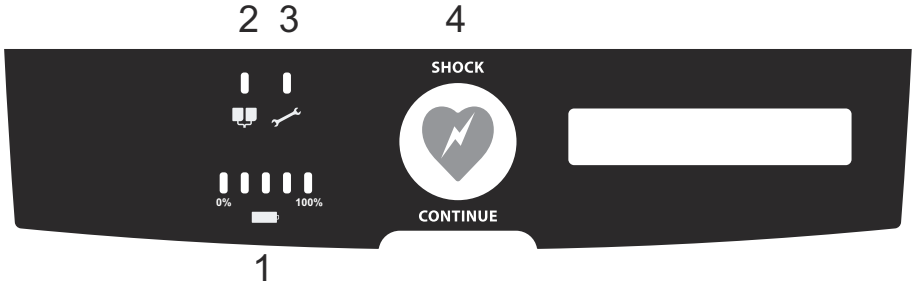
When the STATUS INDICATOR is RED, maintenance is required.

Audible Maintenance Indicator

When the daily, weekly or monthly self-test determines service is required, an audible beep is sounded every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be reactivated.

Diagnostic Panel

The diagnostic panel has the following indicators:



1 SmartGauge Battery Indicator

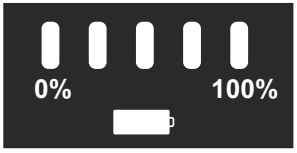
2 Pads Indicator

3 Service Indicator

4 Shock Button

SmartGauge Battery Status Indicator

The SmartGauge Battery Status Indicator has five (5) LEDs, four (4) green and one (1) red. The right four green LEDs display the remaining capacity of the battery much like a fuel gauge. With use, the green LEDs gradually go out, from right to left, as battery capacity decreases. When the green LEDs go out and the red LED lights up, replace the battery.

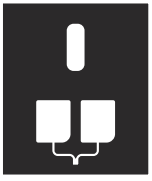


Note: When the red LED initially lights up–upon lid opening or at any time during a rescue–a "Battery Low" prompt will be issued at once. However, the AED is capable of delivering at least 9 more defibrillation shocks after the first "Battery Low" prompt is issued.

When the AED battery cannot deliver any more shocks, the AED display will show "BATTERY LOW", the STATUS INDICATOR will be RED, and the device will "beep" every 30 seconds. To continue the rescue, leave the lid open, remove the battery, and replace with a fresh battery. If battery replacement takes longer than 60 seconds, the first rescue will be terminated and a second rescue will begin upon new battery insertion.

Pads Indicator

The Pads LED lights up when the pads are:



- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged)
- Disconnected from the patient during a rescue

Service Indicator

The Service LED lights up when the AED requires maintenance that can only be performed by qualified service personnel.

Shock Indicator

The AED has one button called the Shock button. The word Shock and the shock button indicator LED will illuminate red when the AED is ready to deliver a defibrillation shock to the patient.

Text Display

The text display has 2 lines of text. The text display provides the operator with information regarding system initialization, text prompts and data during a rescue, and diagnostics.

System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions. The text display also shows the current date and time.

During a rescue, the text display shows the number of shocks delivered and the elapsed time from the beginning of the rescue (when the lid was first opened). During CPR, a countdown timer will be displayed. The text version of the voice prompts will also be displayed.

Note: There is a 3 second delay between the time the AED lid is opened and the start of the rescue. This 3 second delay is not included in the elapsed rescue time.

Setting the AED Internal Clock

The internal clock is preset at Central Standard Time and should be reset to the correct date and local time. If applicable, the AED will automatically adjust itself for Daylight Savings Time. This feature can be turned off using the MDLink software. To set the clock, you will need a Windows 98 or newer PC, RescueLink software installed, and the AED serial cable connected to the PC.

To set the clock settings:

1. Ensure that the PC is set at the correct local time and date.
2. Open the lid of the AED and run the RescueLink software on the PC.
3. Connect the cable to the serial port on the AED.
4. Verify that the voice prompt states “Communications Mode”.
5. Click Communications on the main menu. Select AED Date and Time.
6. Click on the Get button to review the current time in the AED.
7. If the time and date is incorrect, click Set to set new time and date. The AED date and time will automatically be updated to the PC’s time and date.

Voice Prompts and Text Display

The voice prompts activate when the AED lid is opened and help guide the operator through the rescue. The AED text display provides a visual display of most of the audible voice prompts.

The following table lists the voice and text prompts and a description of when the prompts are issued.

Table 4: Voice and Text Prompts

Voice Prompt	Text Display	Situation
“Tear Open Package and Remove Pads.”	TEAR OPEN PACKAGE REMOVE PADS	When the lid is opened, this phrase is repeats twice to initiate the rescue sequence.
“Peel One Pad from Plastic Liner.”	PEEL ONE PAD FROM PLASTIC LINER	Repeats until one pad is peeled off of the liner.

Table 4: Voice and Text Prompts

Voice Prompt	Text Display	Situation
"Place One Pad on Bare Upper Chest."	PLACE ONE PAD ON BARE UPPER CHEST	Repeat twice while one pad is placed.
"Peel Second Pad and Place on Bare Lower Chest as Shown."	PEEL SECOND PAD PLACE ON LOWER CHEST	Repeats until both pads are placed on the patient.
"Do Not Touch Patient! Analyzing Rhythm."	DO NOT TOUCH PATIENT ANALYZING RHYTHM	When the AED is analyzing the cardiac rhythm of the patient.
"Shock Advised."	SHOCK ADVISED	When the AED is preparing to deliver a defibrillation shock.
"Charging."	CHARGING	Repeats while AED is charging.
"Stand Clear! Push Flashing Button to Deliver Shock."	STAND CLEAR PUSH BUTTON TO SHOCK	After the AED is fully charged and ready to deliver the defibrillation shock. The RED Shock indicator flashes and the phrase repeats for 30 seconds or until the Shock button is pushed.
"Shock Delivered."	SHOCK DELIVERED	After the AED delivers a defibrillation shock
"It is now safe to touch the patient."	IT IS NOW SAFE TO TOUCH THE PATIENT.	Advises the rescuer when it is safe to touch the patient.
"Give 30 compressions Then Give Two Breaths"	30 COMPRESSIONS 2 BREATHS	Perform CPR for 2 minutes.
"Check Pads"	CHECK PADS	Occurs when patient impedance is too low or too high.
"Start CPR"	START CPR	After the AED delivers a defibrillation shock After the AED detects a non-shockable rhythm.

Table 4: Voice and Text Prompts

Voice Prompt	Text Display	Situation
"Battery Low"	BATTERY LOW	Occurs once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to do a rescue, the following will occur: **1** "BATTERY LOW" will show on the LCD **2** STATUS INDICATOR will turn RED **3** AED will BEEP once every 30 seconds You must replace the battery before continuing with the rescue. If completely depleted, all AED activity will terminate.
(none)	REMOVE BATTERY COMPLETELY	The AED will show "REMOVE BATTERY COMPLETELY" when the battery is partially removed. But when the battery is at the replace level (showing BATTERY LOW), the REMOVE BATTERY COMPLETELY will not be shown, only the BATTERY LOW.
"Analysis Interrupted. Stop Patient Motion."	ANALYSIS INTERRUPTED STOP PATIENT MOTION	When the AED detects ECG noise artifact, stop moving or touching the patient. Remove other electronic devices within a 5 meter radius.
"Open Lid to Continue Rescue"	OPEN LID TO CONTINUE RESCUE	When the lid is inadvertently closed during a rescue, this prompt will repeat for 15 seconds.
"Rhythm Changed. Shock Cancelled."	RHYTHM CHANGED. SHOCK CANCELLED	When the device is prepared to shock then detects a change in rhythm and therefore cancels the shock.
"Continue CPR"	CONTINUE CPR	During CPR mode when enabled, or when a rescue is resumed in CPR mode after being interrupted by the lid closing.
"Remove Cable to Continue Rescue."	REMOVE CABLE	When a serial communication cable is connected to the AED during a rescue, the phrase repeats until the cable is disconnected.

Table 4: Voice and Text Prompts

Voice Prompt	Text Display	Situation
"Communications Mode"	COMMUNICATIONS MODE	When the lid is open and the serial communication cable is plugged into the AED.
(Beep)		One "Beep" occurs in 30-second intervals during CPR when enabled by the MDLink software program, "Beep" occurs when the AED requires maintenance.
"Service Required"	SERVICE REQUIRED	Occurs after the self-tests determine that the AED is not functioning properly. The prompt "Service Required" will be heard when the lid is opened. The red Service indicator will illuminate and "Service Required" will repeat until you close the lid. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted.

4 Instructions For Use

What's in this chapter

- Warnings and Cautions
- Step 1: Assessment
- Step 2: Preparation
- Step 3: Place Pads
- Step 4: ECG Analysis
- Step 5: Shock Delivery
- Step 6: CPR Mode
- Step 7: Post Rescue

This section presents information about how to use the AED to perform a rescue.

Warnings and Cautions

The following cautions must be observed to prevent problems during the rescue.

DANGER: Fire and Explosion Hazard

Do not use in the presence of flammable gasses (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard

Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage

Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Electric Shock and Fire Hazard

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

CAUTION: Use only Cardiac Science Approved Equipment

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance

Using pads that are damaged or expired may result in improper AED performance.

CAUTION: Serial Communication Cable

The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove cable to continue rescue" will be heard until you remove the serial communication cable from the AED.

CAUTION: Possible Radio Frequency (RF) Susceptibility.

RF susceptibility from cellular phones, CB radios, and FM 2-way radios may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

CAUTION: Possible Interference with Implanted Pacemaker.

Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock. (Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.).

When placing pads:

- Do not place the pads directly over an implanted device.
- Place the pad at least an inch from any implanted device.

CAUTION: Moving the Patient During a Rescue.

During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

Step 1: Assessment

Determine that the patient is over 8 years of age or weighs more than 55 pounds (25 kg) and exhibits the following:

- The patient is unresponsive, and
- The patient is not breathing

Step 2: Preparation

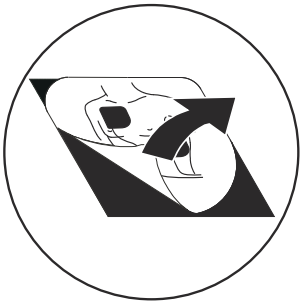
Remove clothing from the patient's chest. Ensure the skin site is clean and dry. Dry the patient's chest and shave excessive hair if necessary.

Open the AED lid and wait until the LEDs are lit.

Note: When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Pads. Therapy should not be delayed to determine the patient's exact age or weight. See the directions for use accompanying pediatric pads for procedure on changing adult pads to pediatric.

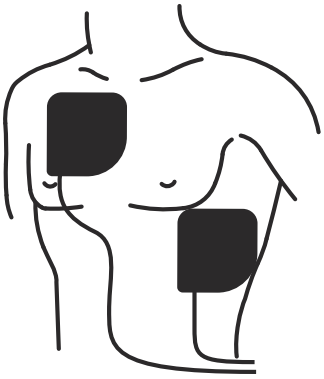
Step 3: Place Pads

The AED will issue the prompt "Tear Open Package and Remove Pads." Keep the pads connected to the AED, tear the pad package along the dotted line and remove the pads from the package. Leave the package attached to the pad wires.



CAUTION: Equipment Damage.
Do not to use lead wires to pull pad from plastic liner.

After the prompt "Peel One Pad From Plastic Liner," with a firm, steady pull, carefully peel one pad away from the plastic liner.



Then, after the prompt "Place One Pad on Bare Upper Chest," place the pad with the sticky side of on the patient's skin on the upper right chest, placing the top of the pad on the collarbone. Avoid placing the pad directly over the sternum.

Finally, after the prompt "Peel Second Pad and Place on Bare Lower Chest As Shown," pull the second pad from the plastic liner and place it on the lower left chest, below and left of the breast.

Note: Cardiac Science's defibrillation pads are non-polarized and can be placed in either position as shown on the pad package.

When the pads are placed, the voice prompt will say "Do not touch patient. Analyzing Rhythm." If the pads are not properly placed or become

disconnected at any time during the rescue, the voice prompt “Check Pads” will be heard. When this occurs, ensure that:

- Pads are firmly placed on clean, dry skin
- Pad cable is securely plugged into the AED

Step 4: ECG Analysis

As soon as the AED detects proper pad placement, the voice prompt “Do not touch patient. Analyzing Rhythm” will be heard. The AED will begin to analyze the cardiac rhythm of the patient.

If a shock is advised, the voice prompt will say, “Shock Advised. Charging.”

When the AED is charged, it continues to analyze the patient’s heart rhythm. If the rhythm changes and a shock is no longer needed, the AED will issue the prompt “Rhythm Changed. Shock Cancelled,” disarm and initiate CPR.

If no shock is advised, the AED will prompt to start CPR.

If noise is detected during analysis, the AED will warn you with the prompt “Analysis Interrupted. Stop Patient Motion” and restart the analysis. This usually occurs if the patient is excessively jostled or there is a strong electromagnetic emitting electronic device nearby (within 5 meters). Remove the electronic device or stop the excessive motion when you hear this prompt.

Step 5: Shock Delivery

When the AED is ready to deliver a defibrillation shock, the Shock button will flash and the prompt “Stand Clear. Push Flashing Button to Deliver Shock” will be heard.

Make sure no one is touching the patient and push the Shock button to deliver a defibrillation shock. If you do not push the Shock button within 30 seconds of hearing the prompt, the AED will prompt “It is safe to touch the patient”. The AED will then prompt you to start CPR.

After the AED delivers a defibrillation shock, the voice prompt will say “Shock Delivered.” The AED will then prompt “It is safe to touch the patient”. The AED will prompt you to start CPR.

Note: During a rescue, the text screen displays voice prompts, elapsed time of rescue and number of shocks delivered.

Step 6: CPR Mode

After shock delivery or detection of a non-shockable rhythm, the AED automatically enters CPR mode. The voice prompt will say, "It is now safe to touch the patient. Start CPR."

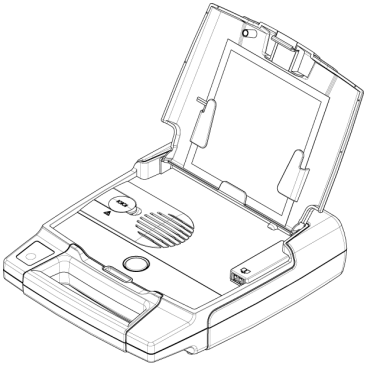
During the CPR time-out period. The AED will not interrupt the CPR mode if the patient's condition changes and the AED detects a shockable rhythm. After the CPR time-out period has expired, the voice prompt "Do Not Touch Patient. Analyzing Rhythm." will be heard.

Note: During CPR mode, the text screen displays a countdown timer.

If the patient is conscious and breathing normally, leave the pads on the patient's chest connected to the AED. Make the patient as comfortable as possible and wait for Advanced Life Support [ALS] personnel to arrive. Continue to follow the voice prompts until the ALS personnel arrive, or proceed as recommended by the Medical Director.

Step 7: Post Rescue

After transferring the patient to ALS personnel, prepare the AED for the next rescue:



1. Retrieve the rescue data stored in the internal memory of the AED by using RescueLink software installed on a PC (see detailed procedure in the Data Management section).
2. Connect a new pair of pads to the AED.
3. Close the lid.
4. Verify that the Status Indicator on the handle is GREEN.

5 Data Management

What's in this chapter

- Recording Rescue Data
- Reviewing Rescue Data
- Multiple Rescue Functionality

The AED is designed for ease of data management and review. The data stored in internal memory can be displayed on the PC screen using the RescueLink software.

Recording Rescue Data

The AED automatically stores up to 60 minutes of rescue data in internal memory.

Reviewing Rescue Data

To retrieve data from internal memory:

1. Open the AED lid.
2. Connect the serial cable to the PC and to the AED's serial port under the blue rubber data access cover. The voice prompt will say "Communications Mode."
3. Run the RescueLink software program.
4. Select Communications, Get Rescue Data. On the RescueLink software program.
5. Select Internal Memory of AED then select OK.
6. Select a rescue by clicking on the date and press OK.

WARNING: Electric Shock and Fire Hazard.

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

CAUTION: Serial Communication Cable.

The serial communication cable is only for use with the AED; it is not to be used with a telephone.

Multiple Rescue Functionality

The AED can store up to 60 minutes of ECG monitoring time in the AED's internal memory. Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC. Should the internal memory become full, the AED will purge rescues as needed, beginning with the oldest rescue.

When downloading data, RescueLink will enable the user to select which rescue to download. See the RescueLink application help files for more information.

6 Maintenance and Troubleshooting

What's in this chapter

- Self-Tests
- Indicator Troubleshooting Table
- Scheduled Maintenance
- Authorized Repair Service
- Frequently Asked Questions

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

Self-Tests

The AED has a comprehensive self-test system that automatically tests the electronics, battery, pads, and high voltage circuitry. Self-tests are also activated every time you open and close the AED lid.

When performing the self-tests, the AED completes the following steps automatically.

1. Turns itself ON, and the Status Indicator changes to RED.
2. Performs the self-test.
3. If successful, the Status Indicator reverts to GREEN.
4. Turns itself OFF if the lid is closed.

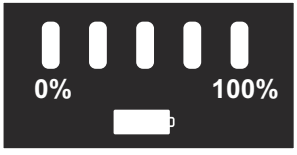
There are three types of automatic self-tests. The Daily Self-test checks the battery, pads, and the electronic components. The Weekly Self-test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-test. During the Monthly Self-test, the high voltage electronics are charged to full energy.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the Status Indicator will remain RED. Upon closing the lid, an audible alert will be issued. The Diagnostic Panel under the lid will indicate the source of the problem according to the Indicator Troubleshooting Guide Table on the next page.

Indicator Troubleshooting Table

The following is a troubleshooting table for the AED indicators.

Table 5: Indicator Troubleshooting Table

View	Symptom	Solution
	Red SERVICE indicator (LED) is lit.	Maintenance by authorized service personnel is required. Call Cardiac Science Customer Service (see page 4) or your local Cardiac Science distributor.
	Red Pads indicator (LED) is lit.	Connect the pads or replace with a new pair.
	The last battery indicator (LED) is red.	The battery is low. Replace with a new battery.
	Status INDICATOR is RED, and no other indicators on the diagnostic panel are lit.	The battery power is completely depleted. Replace with a new battery. If Status INDICATOR remains RED call Cardiac Science Customer Service or your local Cardiac Science distributor.

CAUTION: Temperature Extremes.

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AED's operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Chapter 7, *Technical Data*.

Scheduled Maintenance

Perform the following tests per the schedule indicated:

Daily Maintenance

Check the Status Indicator to ensure that it is GREEN. When the indicator is GREEN, the AED is ready for a rescue. If the indicator is RED, refer to the Troubleshooting Table in this chapter.

Monthly Maintenance

Perform the following procedure each month (28 days)

1. Open the AED lid.
2. Wait for the AED to indicate status: Observe the change of the STATUS INDICATOR to RED. After approximately 5 seconds, verify that the STATUS INDICATOR returns to GREEN.
3. Check the expiration date on the electrodes.
4. Listen for the voice prompts.
5. Close the lid and observe the change of the STATUS INDICATOR to RED. After approximately 5 seconds, verify that the STATUS INDICATOR returns to GREEN.

Annual Maintenance

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.

Check the Integrity of the Pads and Circuitry:

1. Open the AED lid.
2. Remove the pads.

3 Close the lid.

4 Confirm that the STATUS INDICATOR turns red.

5 Open the lid and confirm that the Pad indicator is lit.

6 Reconnect the pads and close the lid.

7 Make sure the expiration date is visible through the clear window of the lid.

8 Check to make sure that the STATUS INDICATOR is GREEN. If the pads are not installed properly, the PAD indicator will illuminate; call Customer Service for assistance.

9 Open the lid and confirm that no diagnostic indicators are lit.

10 Check the expiration date of the pads; if expired, replace them.

11 Check the pads packaging integrity.

12 Close the lid.

Check the Integrity of the Service Indicator (LED) and Circuitry:

1 Immediately after opening the AED lid, press and hold the Shock button and confirm that the Service LED is lit.

2 Release the Shock button.

3 Close the lid.

4 Verify that the STATUS INDICATOR remains red.

5 Open the lid and confirm that no diagnostic indicators are lit.

6 Close the lid.

7 Verify that the STATUS INDICATOR turns red then green.

Check the Integrity of the Case:

Examine the molded case of the AED for any visible signs of stress. If the case shows signs of stress, contact Cardiac Science Customer Service (See page 4) or contact your local Cardiac Science distributor.

CAUTION: Case Cleaning Solutions.

When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

Authorized Repair Service

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Cardiac Science Customer Service (See page 4) or contact your local Cardiac Science distributor.

WARNING: Shock Hazard.

Do not disassemble the AED. Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.

Note: The warranty will be void upon unauthorized disassembly or service of the AED.

Frequently Asked Questions

Q: Can I give CPR while the AED is analyzing?

A: No. As with all AEDs, the operator should stop CPR compressions during the analysis phase.

Q: Can I transport the victim while the AED is analyzing?

A. No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.

Q: Do I need to prepare the chest prior to pad application?

A: Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as possible. Follow your Medical Director's instruction.

Q: What happens if the battery is low when I begin a rescue?

A: When the battery indicator is red, the AED issues a "Battery Low" prompt once; however, the AED is still capable of delivering approximately 9 more defibrillation shocks.

When the AED is not capable of delivering any more shocks, it "beeps" once every 30 seconds.

To continue the rescue attempt, leave the lid open and replace the battery. When the battery replacement takes longer than 60 seconds, the first rescue

is terminated and the AED will begin to record the events from then on as a separate rescue.

Q: How do I set the AED internal clock?

A: Set the clock by using the RescueLink Software Program and a PC. See Setting the AED Internal Clock in Chapter 3.

Q: What happens if I close the lid in the middle of a rescue attempt?

A: If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. You will hear the prompt, "Open lid to continue Rescue." If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is reopened.

Note: If the lid is closed during a rescue while the pads are connected to the patient, the STATUS INDICATOR may turn RED. When the lid is reopened, however, the rescue may be continued even though the STATUS INDICATOR remains RED.

Q: My AED is sounding an audible alert. Why? How do I stop it?

A: The audible alert indicates that the self-test detected a need for maintenance or corrective action. Determine the maintenance required by using the Troubleshooting Table in this chapter. Opening and closing the lid may turn OFF the audible alert until the next self-test. However, the STATUS INDICATOR will remain RED.

Q: The AED did not sound an audible alert when I removed the pads and closed the lid. Why?

A: The lid-closed pad self-test only activates the STATUS INDICATOR. The AED allows time for replacement of the pads – as removing pads is a normal procedure after a rescue – or a battery during the post rescue procedure, however, an audible maintenance indicator will be triggered after the next Daily Self-test.

Q: What if I have to perform a rescue in an isolated area and at subzero temperatures?

A: When travel to a rescue involves exposing the AED to extremely cold temperatures for an extended period of time, keep the pads and the battery warm.

7 Technical Data

What's in this chapter

- Parameters
- Star Biphasic Waveform

This section lists the AED parameters.

Parameters

Table 6: Parameters

Parameter	Detail
Operation	Semi-Automatic (shock advisory) Automatic
Audible Alerts	Voice Prompt Maintenance Alert
Visible Indicators	Status Indicator Battery Status Indicator Service Indicator Pads Indicator Text Display
Rescue Data Storage	Internal with 60 minutes ECG data with event annotation
Dimensions	Height: 8 cm (3.3 in) Width: 27 cm (10.6 in) Depth: 31 m (12.4 in)
Weight (Batteries and Pads)	CardioVive AT: 3.10 kg (6.6 lb)

Table 6: Parameters

Parameter	Detail
Environmental Operation and Standby Conditions	Temperature: 0°C to 50°C (32°F to 122°F) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Shipment and Transport environmental Conditions (for up to 1 week)	Temperature: -30°C to 65°C (-22°F to 149°F) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Pads	Self-adhesive, disposable defibrillation pads Minimum combined surface area: 228cm^2 Extended length of lead wire: 1.3m
9146 Lithium Battery Specifications (p/n: 9146-001-C1)	Output voltage: 12VDC (max) Batteries are non-rechargeable Lithium contents: 9.2g (max) Check local regulations for disposal information Full Operational Replacement Guarantee (from date of installation): 4 Years Estimated Shelf Life (from date of manufacture): 5 Years Typical Shocks: up to 290 shocks **Note:** The battery operating life depends on the type of battery, actual usage and environmental factors.
Batteries and Capacitor Charge Times	A new battery typically takes 10 seconds to charge the AED to maximum energy. A battery with reduced capacity causes the red LED light to initially turn ON and typically takes 13 seconds to charge a fully discharged AED to maximum energy. The maximum time from "Power On" to "Ready to Shock" is 55 seconds for a new rescue. The maximum time from "Analyze" to "Ready to Shock" is 55 seconds for a new rescue.

Table 6: Parameters

Parameter	Detail
AED Self test Sequence	Daily: Battery, pads, internal electronics, shock button, and software (no charge). Weekly: Battery, pads, internal electronics, shock button, and software (partial charge). Monthly (every 28 days): Battery under load, pads, internal electronics, full-energy charge cycle, shock, and software (full charge). Open Lid (when lid is opened): Battery, pads, internal electronics, shock button, and software. Close Lid (when lid is closed): Battery, pads, internal electronics, shock button, and software.

Table 6: Parameters

Parameter	Detail
Safety and Performance	CardioVive AT The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The CardioVive AT and pads conform to the applicable requirements of the following: 0086 CE CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC of European Nations ETL Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Table 6: Parameters

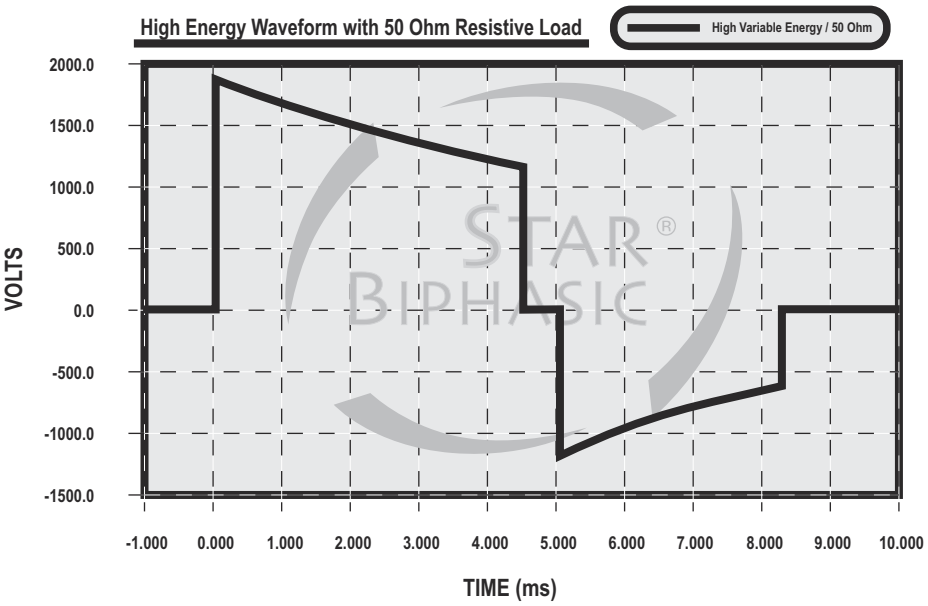
Parameter	Detail
	Electrical, Construction, Safety and Performance IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995) IEC 60601-2-4 (2002) ANSI/AAMI DF-39 (1993) Electromagnetic Compatibility (EMC) IEC 60601-1-2 (2001) IEC 60601-2-4 Section 36 ANSI/AAMI DF-39 (1993) Section 3.3.21
Emissions	EM: EN 55011/CISPR 11, Group 1, Class B Magnetic: ANSI/AAMI DF39, <0.5mT on surface, except for within 5cm of the lid magnet and the speaker
Immunity	EM • EC 61000-4-3, Level X, (20V/m) • EC 60601-2-4, Section 36.202.3 (20V/m) • AAMI DF39, Section 3.3.21.2.1 Magnetic • IEC 61000-4-8 (2001) • IEC 60601-2-4 (2002), Section 36.202.8 • AAMI DF39, Section 3.3.21.2.3 80A/m, 47.5Hz – 1,320Hz ESD • IEC 61000-4-2, Level 3 • IEC 60601-2-4 (2002), Section 36.202.2 • 6KV contact discharge, 8KV air gap discharge
Environmental Conditions	Free Fall Drop: IEC 60068-2-32 (1975) AM 2 (1990), 1 meter Bump: IEC 60068-2-29 (1987), 40g and 6000 bumps Vibration (Random): IEC 60068-2-64 (1993): 10Hz – 2KHz, 0.005 – 0.0012 g^2/Hz Vibration (Sine): IEC 60068-2-6 (1995): 10Hz – 60Hz, 0.15 mm and 60Hz – 150Hz, 2g Enclosure Protection: IEC 60529 (2001), IP24

Table 6: Parameters

Parameter	Detail
Shipping and Transportation Conditions	ISTA Procedure 2A
RHYTHMx ECG Analysis Performance	The AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm. This system makes it possible for a person, with no training in the interpretation of ECG rhythms, to offer defibrillation therapy to victims of sudden cardiac arrest.
Cardiac Rhythms Used to Test the Rhythm Recognition Detection System for CardioVive AT AEDs	Shockable Rhythm* – VF: Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >90% (*Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety, AHA AED Task Force and approved by the AHA Science Advisory and Coordinating Committee. Circulation, 1997(95), pp 1677-1682) Shockable Rhythm – VT: Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >75% Non-shockable Rhythm – NSRMeets AAMI DF 39 requirement (>95%) and AHA recommendation (>99%) of Specificity Non-shockable – Asystole: Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95% Non-shockable: Meets AAMI DF 39 requirement and AHA recommendation of Specificity – all other rhythms of >95%

Star Biphasic Waveform

The waveform generated by the CardioVive AT AED is a Biphasic Truncated Exponential waveform that is compliant with ANSI/AAMI DF2 and DF39. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50 Ohm resistive load.



The Biphasic Truncated Exponential (BTE) waveform uses variable energy. The actual energy delivered will vary with the patient's impedance and the device will deliver a shock when impedance is between 25-180 Ohms. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy, and high variable energy as shown in the waveform tables on the following pages.

Table 7: Ultra-low VariableEnergy (150 VE) CardioVive AT Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	**Voltage* (Volts)**	**Duration* (MS)**	**Voltage* (Volts)**	**Duration* (MS)**	**Energy** (Joules)**
25	1393	3.3	743	3.2	145-196
50	1420	4.5	909	3.2	128-173
75	1430	5.8	973	3.2	108-146
100	1434	7.0	1007	3.2	108-146
125	1437	8.3	1027	3.2	102-138
150	1439	9.5	1040	3.2	98-132
175	1441	10.8	1049	3.2	95-128

Table 8: Low Variable Energy (200 VE) CardioVive AT Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	**Voltage* (Volts)**	**Duration* (MS)**	**Voltage* (Volts)**	**Duration* (MS)**	**Energy** (Joules)**
25	1609	3.3	858	3.2	193-260
50	1640	4.5	1050	3.2	170-230
75	1651	5.8	1124	3.2	155-209
100	1656	7.0	1163	3.2	144-194
125	1660	8.3	1186	3.2	136-184
150	1662	9.5	1201	3.2	131-176
175	1663	10.8	1212	3.2	126-170

Table 9: High Variable Energy (300 VE) CardioVive AT Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	**Voltage* (Volts)**	**Duration* (MS)**	**Voltage* (Volts)**	**Duration* (MS)**	**Energy** (Joules)**
25	1869	3.3	997	3.2	260-351
50	1906	4.5	1220	3.2	230-311
75	1918	5.8	1306	3.2	210-283
100	1925	7.0	1351	3.2	195-263
125	1928	8.3	1378	3.2	184-248
150	1931	9.5	1396	3.2	176-238
175	1933	10.8	1408	3.2	170-230

* All values are typical.

** Allowable energy range.